

REMARKS

Claims 18, 19, 21-24, 26-28, 31-35, 41-48, and 50-52 are pending. Claims 18 and 19 are amended. Support for the amendments is found throughout the specification at, inter alia, page 2, line 31-page 3, line 3 and page 3, lines 26-31. Thus, it is believed that no new matter has been added. No claim is allowed.

Rejections Under 35 U.S.C. § 103

Claims 18-19, 21-24, 26-28, 31-35, 41-48 and 50-52 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the combination of Nielson (WO 95/28850) in view of Ghani (U.S. Patent No. 6,120,811) for reasons of record. Claims 22-23 and 46-47 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the combination of Nielson (WO 95/28850) in view of Ghani (U.S. Patent No. 6,120,811) and further in view of Markussen (U.S. Patent No. 4,106,991) for reasons of record. Claims 18-19, 21-22, 24-28, 31-35, 41-46 and 48-52 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the combination of Nielson (WO 95/28850) in view of Ghani (U.S. Patent No. 6,120,811) and further in view of Haarasilta (GB 2-139868A) for reasons of record. Claims 23 and 47 are rejected as allegedly unpatentable under 35 U.S.C. § 103(a) over the combination of Nielson (WO 95/28850) in view of Ghani (U.S. Patent No. 6,120,811) and further in view of Haarasilta (GB 2-139868A) as applied to claims 22 and 46 and further in view of Markussen (U.S. Patent No. 4,106,991) for reasons of record. Applicants traverse this rejection for reasons already of record as well as those discussed above.

The obviousness analysis under 35 U.S.C. § 103(a) requires the consideration of the scope and content of the prior art, the level of skill in the relevant art, and the differences between the prior art and the claimed subject matter must be considered. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966))(emphasis added). “Rejections on obviousness grounds cannot be sustained by mere conclusory statements.” *In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2007) (citations omitted). Critical elements of the invention as a whole which clearly distinguish the entire invention from the prior art references cannot be ignored. *Panduit Corp. v. Dennison Manufacturing Co.*, 1 U.S.P.Q.2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). Evidence of an unobvious or unexpected advantageous property can rebut *prima facie* obviousness. MPEP §

716.02(a). Moreover, if a modification changes the principle of operation of a reference, the teachings of that reference do not render the claimed invention obvious. MPEP § 2142.01.

Applicants respectfully submit that none of the cited combination of references teach or suggest an extruded high activity phytase-containing granulate having increased pelleting stability using starch as the non-fibrous carrier. As disclosed in the instant specification, the claimed granulates shows increased pelleting stability. *See, e.g.*, the specification at Examples 5 and 10. More particularly, in Example 5, the high activity phytase granulate demonstrates an significantly increased enzyme yield (*e.g.*, <17% enzyme yield in a low activity pellet versus 48% enzyme yield in the high activity pellet). In Example 10, the residual activity in pelleted granulates having approximately 600 and 4200 FTU/g differed by only 3%, suggesting that a significantly higher amount of FTU/g would be required to further increase the activity. However, when the pellet was formulated at approximately 6800 FTU/g, an additional 3% residual activity was retained, providing additional evidence of an unexpected advantageous increase in pelleting stability in the claimed granulates.

Nielson lacks any disclosure relating to pelleting stability in high activity phytase granulates. Nielson merely describes a feed additive comprising one or more phytase enzymes and one or more proteolytic enzymes that can be added to extruded feed. Nielson is completely silent regarding pelleting stability of the enzyme preparation. Moreover, Nielson fails to teach or suggest the extrusion of high activity phytase granulates using starch, a non-fibrous carrier (as previously acknowledged by the Examiner).

Ghani fails to cure these deficiencies. As previously discussed, Ghani's lacks any disclosure relating to the use of *solely* a non-fibrous carrier in a high activity phytase, extruded granulate. Ghani discloses gentler preparation methods such as spray-drying, fluid bed granulation, or high-shear granulation with no discussion of extrusion. Such methods differ from the extrusion process in that they typically have lower pressure and temperature processing conditions. Therefore, the success of a particular enzyme formulation in these gentler preparation methods provides no guidance or insight to a person of ordinary skill in the art. Fibrous carriers generally stabilize the granules, and thus are favored to include in enzyme formulations of this type. Nothing in Ghani discloses or even hints that fibrous carriers are not required. Ghani also fails to provide any suggestion that such an enzyme granulate has significantly greater pelleting stability or can even be successfully formed in the absence of a fibrous carrier.

Likewise, Markussen fails to remedy the deficiencies in Nielson or Nielson and Ghani. Markussen's disclosure is limited to a granulate requiring a fibrous carrier (*i.e.*, cellulose) and describes the cellulose as responsible for one of the advantageous properties of the disclosed granulate (*i.e.*, the absence of an unwanted layer of starting material on the walls of the granulator). Markussen is completely silent regarding enzyme granulates using non-fibrous carriers or the pelleting stability of high activity phytase granulates. In fact, to modify Markussen to result in the claimed granulate of the instant application where a fibrous carrier is **not** employed would impermissibly change the principle of operation of Markussen's invention. Thus, Markussen cannot be properly combined with the cited references.

Haarasilta also fails to cure the deficiencies in the cited combinations of references. Haarasilta discloses extrusion only with respect to extruding foodstuffs which contain fibrous components. These fibrous include hay or straw, a distinct carrier from the non-fibrous starch of the claimed granulates. As with Markussen, modification of Haarasilta to result in the claimed granulate of the instant application where a fibrous carrier is **not** employed would impermissibly change the principle of operation of Haarasilta's invention. *See* Haarasilta at page 1, lines 10-21. Thus, Haarasilta cannot be properly combined with the cited references. Haarasilta also lacks any disclosure relating to pelleting stability of granulates having various enzyme activity levels.

Applicants note that the Office continues to allege that one of skill in the art would be motivated to make granulates without fibrous materials to avoid mechanical malfunctions in the extruder and to produce smaller granules without providing a rationale for discounting the teachings of the very references cited in the rejections. For example, Markussen describes granulation of enzymes as "a difficult task" that is "extremely difficult to control". *See* Markussen at col. 1:35-40 and col. 2:1-15. Applicants note that all of the references teach that the inclusion of fibrous materials in the disclosed enzyme granulates. Thus, each and every reference discloses distinct granulates from the claimed granulate. "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, [the Office] must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law." *In re Kahn*, 441 F.3d at 98. Applicants respectfully submit that the Examiner has not yet provided a rationale, articulation or reasoned

basis for why a skilled artisan would forego the use of a fibrous carrier in an enzyme granulate, particularly in view of the teachings that such a carrier is required.

For at least these reasons, the rejections under 35 U.S.C. § 103 are overcome and may be removed.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **251502008600**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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